REMARKS

Claims 11-13 currently appear in this application. The Office Action of January 18, 2002, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Rejections under 35 U.S.C. 112

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is respectfully traversed. It is not understood why claim 11 is said to be indefinite. Claim 11 has been amended to recite that, if the test for a, b, or c is positive, concluding that the donor or potential donor is a carrier of a disease or condition related to at least one of HTLV-I or HTLV-II.

With respect to the limitation "...a sample from the donors...", claim 11 has been amended to recite "testing a sample from a donor or a potential donor..." The sample is tested for the presence of a DNA which encodes either the HTLV-I tax protein or the HTLV-II tax

protein. The sample is tested for at least one of the infections comprising HTLV-I or HTLV-II, although the donor or potential donor could be infected with either one or both.

Claim 13 has been amended to correct the self-evident typographical error.

Art Rejections

Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Zucker-Franklin et al. (*The Lancet* **349**:999, 1997). The Examiner alleges that this article teaches screening of 100 healthy potential blood donors for the presence of HTLV-I tax DNA by PCR, and the donors were tested for the presence of antibodies to the tax protein. No other tests for the detection of HTLV-I or HTLV-II viruses were performed.

This rejection is respectfully traversed. The present invention is directed to a method for screening healthy blood donors or potential blood donors to determine if these persons are carriers of diseases or conditions related to at least one of HTLV-I or HTLV-II. This screening is effected by testing a sample from the donor for the presence of a DNA which encodes the HTLV-I tax protein or the HTLV-II tax protein. The presence of the HTLV-I tax protein or the HTLV-II tax protein indicates the presence of:

a. at least one of the HTLV-I tax protein or the HTLV-II tax protein;

b. DNA which encodes at least one of HTLV-I tax protein or HTLV-II tax protein; and

c. antibodies specific to at least one of HTLV-I or HTLV-II tax protein.

If the test is positive, it is concluded that the donor or potential donor is a carrier of a disease or condition related to at least one of HTLV-I or HTLV-II infection.

Zucker-Franklin et al, in *The Lancet* article, note in paragraph 2 of the article that the test was performed on potential donors who are negative for antibodies to HTLV-I/II by standard serological tests used in U.S. blood-transfusion centers. The implication here is that the persons tested had already tested negative on standard serological tests. This is contrary to the present invention, in which the persons tested had not been tested for antibodies to at least one of HTLV-I or HTLV-II, or had not been subjected to any screening test specifically to test for infection by HTLV-I or HTLV-II.

In view of the above, it is respectfully submitted that the claims are now in condition for

allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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11. (Amended) A method for screening healthy blood donors or potential blood donors for carriers of diseases or conditions related to at least one of HTLV-I and HTLV-II infections comprising:

testing a sample from [redacted] or potential [redacted] for the presence of a DNA which encodes the HTLV-I tax protein or the HTLV-II tax protein;

wherein a positive test for the presence of a DNA which encodes the HTLV-I tax protein or the HTLV-II tax protein indicates the presence of:

a. at least one of HTLV-I or HTLV-II tax protein;

b. DNA which encodes at least one of HTLV-I or HTLV-II tax protein; and

c. antibodies specific to at least one of HTLV-I or HTLV-II tax protein;

[redacted] and, if the test for at least one of (a), (b), or (c) is positive, [redacted] that the donor or potential donor is a carrier of a disease or condition related to at least one of HTLV-I or HTLV-II infection.

15. (Amended) The method according to claim 11 wherein said testing comprises subjecting each sample from the donors or potential donors to a test for the presence of DNA which encodes at least one of HTLV-I or HTLV-II tax protein, in the absence of any screening test specifically provided to test for infection with at least one of HTLV-I or HTLV-II.